



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/086,253

03/01/2002

Barbara A. Rincavage

RINCAVAGE-1

4031

25101

7590

04/27/2010

Philip D. Freedman PC
1449 Drake Lane
Lancaster, PA 17601

EXAMINER

RINES, ROBERT D

ART UNIT

PAPER NUMBER

3623

MAIL DATE

DELIVERY MODE

04/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/086,253	RINCAVAGE ET AL.	
	Examiner	Art Unit	
	R. David Rines	3623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the response filed 13 January 2010. Claims 21-40 are pending.

* Claims 21-40 have not been amended and are accordingly rejected under 35 U.S.C. 103(a) for the reasons, conclusions of obviousness, and statements of motivation provided in the previous Office Action mailed 16 December 2009 and the Decision of the USPTO Board of Patent Appeals and Interferences issued 3 September 2009 incorporated by reference herein. Applicant's remarks filed 13 January 2010 are addressed below.

Response to Remarks

[2] Applicant's remarks filed 13 January 2010 have been fully considered but they are not persuasive. The remarks will be addressed below in the order in which they appear in the noted response.

Applicant's remarks directed to previous rejection(s) under 35 U.S.C. 112, second paragraph are moot as the noted rejection(s) have been withdrawn herein.

Art Unit: 3623

Applicant's remarks directed to previous rejection(s) under 35 U.S.C. 101 are moot as the noted rejection(s) have been withdrawn herein.

With respect to the applied teachings of Denny, Borsand as applied to claims 21-40 Applicant remarks:

"...First, Denny and Borsand are not prior art to Applicants' invention....Borsand published April 17, 2003 and Denny published February 3, 2004 are not prior art to the instant [Application] filed March 3, 2002..."

Applicant further provides:

"...35 U.S.C. 102(a) provides that a person shall be entitled to a patent unless the instant invention was...described in a printed publication in the or a foreign country before the invention by the applicant..."

In response, Examiner respectfully disagrees and notes the effective filing date of Denny, 21 September 1999, and the effective filing date of Borsand, 12 October 2001. Examiner further notes that the effective filing dates of both the noted references antedate the filing date of the instant application of 3 March 2002. Accordingly, while Applicant correctly notes that the references fail to qualify as prior art under 35 U.S.C. 102(a), they do qualify as prior art under 35 U.S.C. 102(e), and are therefore appropriately applied under 35 U.S.C. 103(e).

Applicant's remaining remarks substantially rehash arguments addressed in the preceding sections of the instant Office Action, in the previous Office Action, mailed 16 December 2009, and in the Decision by the Board of Patent Appeals and Interferences Affirming Examiner's rejection(s) issued 3 September 2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[3] Previous rejection of claims 31-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been overcome by Applicant's clarifying statements presented in the response filed 13 January 2010 indicating that the recited "processing center", as originally disclosed, is an apparatus. Accordingly, the noted rejection(s) are hereby withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

[4] Previous rejection(s) of claims 21-30 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter have been overcome by Applicant's clarifying statements presented in the response filed 13 January 2010 indicating that the recited "processing center", as originally disclosed, is an apparatus. Accordingly, the noted rejection(s) are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[5] Claims 21-22, 27-30, 31-32, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny (United States Patent Application Publication #2004/0107117) in view of Borsand et al. (United States Patent Application Publication #2003/0074225).

As per claim 21, Denny discloses a prescription fulfillment method, comprising; entering an unfilled prescription prescribed by a physician or medical service provider into a processing center wherein the prescribed prescription comprises at least medication brand or dosage (Denny; paragraphs [0010] [0027] [0030] [0031] [0064]); retrieving an unfilled prescription from the processing center (Denny; paragraphs [0011] [0012] [0032] [0035] [0036] [0064]); filling the prescribed prescription by a pharmacist (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]), wherein the filled prescription is different from the retrieved prescription in respect of at least one of medical brand and dosage; entering the filled prescription into the processing center in fulfillment of the prescribed prescription for review by the prescribing physician or medical service provider (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]).

While Denny provides for the pharmacist inputting information representative or indicative of a prescription to be filled (Denny; paragraph [0035]) and subsequently provides for the pharmacist inputting a code indicating that a prescription has been filled into the host system (Denny; paragraph [0041]), Denny fails to specifically indicate that the pharmacist enters filled prescription data that includes pharmaceutical type, quantity, cost or other information and “wherein the filled prescription is different from the retrieved prescription in respect of at least one or medical brand and dosage..”.

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes information for said presented pharmaceutical type and said presented quantity and “wherein the filled prescription is different from the retrieved prescription in respect of at least one or medical brand and dosage..”. (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118] *see electronic representation of filled prescription).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Denny with those of Borsand et al. Such combination would have resulted in a system and method that enabled the entry of prescription information including prescribed drug and dosage level prescribed to a patient, by a physician, into a host system (Denny; Abstract). Such a method/system would have further provided for the retrieval of the prescribed drug and dosage level information from the host system, by a pharmacist, for the purpose of filling the prescription for the patient (Denny; Abstract). Additionally, such a system/method would have enabled the pharmacist to enter information indicating that the prescription had been filled into the host system for the review of the prescribing physician (Denny; paragraphs [0035] [0041] [0053]). Lastly, such a method would have been enabled by a integrated system in which the payor, PBM, pharmacy, and provider access and manipulate the same information, including prescribed drug, quantity/dosage, refills, cost, and reimbursement

rules (Borsand et al.; paragraphs [0040] [0064]). The motivation to combine the teachings would have been to enable a provider to monitor the filling of a prescription such that the prescription can be cancelled in the event of fraud, abuse, or mistakes, such as a pharmacist filling a prescription at half strength but twice the volume and cost (Borsand et al.; paragraphs [0005] [0120]).

As per claim 22, Denny discloses a method further comprising comparing the different medication brand or dosage of the unfilled prescription with the filled and different medication brand or dosage and generating a warning of the different medical brand or dosage (Denny; paragraph [0053]).

As per claim 27, Denny discloses a method comprising registering medical service professionals authorized to access a database associated with the processing center (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per claim 28, Denny discloses a method wherein entering the filled medication generates a warning signal to the prescribing physician or medical service provider (Denny; paragraph [0053]).

Regarding claim 28, Denny discloses a check for prescription data validity and subsequent messaging to the physician, Denny fail to explicitly recite that the data check specifically check the contents of the filled prescription, i.e., dosage and brand.

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes “filled and different” information (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118] *see electronic representation of filled prescription).

As per claim 29, while Denny discloses a warning mechanism, Denny fails to specifically indicate that the warnings are sent to an insurance company.

However, Borsand et al. disclose a method wherein entering the filled prescription medication generates a warning signal to an insurance company (Borsand et al.; paragraphs [0005] [0034] [0120]-[0122] and Fig. 11).

NOTE: Borsand et al. provide a system and method that supports tracking pharmaceutical, prescription, and related information throughout the life cycle of the pharmaceutical or prescription (Borsand et al.; paragraph [0034]). Borsand et al. further specify that information tracking can be in a proactive and real-time manner (Borsand et al.; paragraph [0034]). Borsand et al. further teach that a purpose of proactive and real-time tracking of information is to identify instances of fraud or error, such as a pharmacist filling a prescription at half strength and half strength and twice the volume and cost (Borsand et al.; paragraph [0005]). Examiner's

interpretation of the above noted teachings of Borsand et al. constitute a "warning" mechanism indicating that a pharmacist has failed to fill a prescription properly.

.

As per claim 30, Denny discloses a method wherein the processing center is accessed by the physician, medical service provider or pharmacist by a telecommunications link (Denny; paragraphs [0023] [0038]).

Regarding claims 22 and 27-30, the conclusions of obviousness and statements of motivation as discussed with regard to claim 21 above are applicable to claims 22 and 27-30 and are herein incorporated by reference.

Claims 31-32 and 37-40 substantially repeat the subject matter presented in method claims 21-22 and 27-30 system form. Accordingly, claims 31-32 and 37-40 are rejected as obvious in consideration of Denny in view of Borsand et al. for the reasons, conclusions of obviousness, and statements motivation as discussed above with respect to claims 21-22 and 27-30.

[6] Claims 23-26 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny and Borsand et al. as applied to claims 1 and 12 above, and further in view of Keresman, III et al. (United States Patent Application Publication #2001/0047281).

Regarding claims 23-26, while Denny teaches authenticating and identifying provider and pharmacist systems accessing the host system (Denny; paragraph [0043]), Denny fails to

Art Unit: 3623

specifically teach biometric identification as part of the security protocol. Borsand et al. fail to disclose biometric authentication.

However, as evidenced by Keresman, III et al., the use of biometric identification of registered doctors, pharmacies, and other participants is well known in the prescription drug fulfillment art (Keresman III et al.; paragraphs [0008] [0009] [0015] [0050] [0056]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Denny and Borsand et al., as applied to claim 1 and 12 above, with those of Keresman, III et al. with the intention of determining that the requesting system is a valid system by using password protection or other security methods known in the art (Denny; paragraph [0043]). The motivation to combine the teachings would have been to employ a well-known security protocol to provide a suitable degree of security, which prevents unauthorized access to a patient's confidential medical and pharmaceutical records (Keresman, III et al.; paragraph [0004]).

Claims 33-36 substantially repeat the subject matter presented in method claims 23-26 in system form. Accordingly, claims 33-36 are rejected as obvious in consideration of Denny in view of Borsand et al. for the reasons, conclusions of obviousness, and statements motivation as discussed above with respect to claims 23-26.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David Rines whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Primary Examiner, Art Unit 3623